K120253 1/2

Elcam MEDICAL

JUL 16 2012

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92

Submitter Information

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Submission contact person:

Ilan Sharon
P.O.B. 4414 (A-109), Caesarea 30889, Israel
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Device Classification

Proprietary Device Name:	Elcam Vital Signs Wireless System
Common name:	Radiofrequency physiological signal transmitter and receiver
Product Code:	DRG
Classification Name:	Transmitters and receivers, physiological signal, radiofrequency
Classification Regulation:	21 CFR § 870.2910
Regulatory Class:	II

Identification of Legally Marketed Predicate Devices

Hospira Vital Signs Wireless Monitoring System - K090610

Device Description

Elcam Vital Signs Wireless System utilizes the Bluetooth® communications Protocol in order to eliminate the multi-conductor, fixed length and shielded reusable cables that typically acts as the interface between the patient's bedside monitor and disposable transducer. The disposable transducer will simply plugs into the system's remote transmitter unit, which sends its output signal to the system's receiver unit affixed to the bedside monitor.
The wireless system is intended to operate at varying distances to accommodate typical layouts that exist within hospital operating rooms, critical care units, emergency rooms and catheterization lab suites.

Intended Use of Device

Elcam Vital Signs Wireless System is indicated for use on patients requiring pressure monitoring. Elcam Vital Signs Wireless System is intended to perform wireless transmission of pressure information to remote patient monitors from disposable pressure transducers.

Safety & Effectiveness

The proposed and predicate devices are similar in design, materials of construction, components, intended use and labeling.
Based on the performance results provided (including test results and clinical data) and the analysis of similarities and differences presented above, Elcam Medical believes that the proposed device safe & effectiveness is substantially equivalent to the predicate device without raising new safety and/or effectiveness issues.

Rational for Substantial Equivalency

Elcam Vital Signs Wireless System is substantially equivalent to the predicate device with respect to the following characteristics:

1. Wireless transmission of physiological characteristics from the patient to the receiver monitor units.
2. Replaces the existing cabling between disposable physiological transducers and bedside monitors in hospital settings.
3. Utilization of the Bluetooth® Technology for wireless transmission of physiological signals.

The claim for substantial equivalence is supported by the information provided in the 510(k) submission

Substantial Equivalence Statement

Based on the above, it is Elcam Medical's opinion that the proposed Vital Signs Wireless System is substantially equivalent in terms design principles, performance features and of safety & effectiveness to the legally cleared predicate device (K090610) referred to in chapter 4 of this 510(K) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 16 2012

Elcam Medical A.C.A.L.
c/o Ilan Sharon
Submission Correspondent
P.O.Box 4262
Zichron Yaacov
Israel, 30900

Re: K120253
Trade/Device Name: Elcam Vital Signs Wireless System™ (VSWS)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: June 14, 2012
Received: June 19, 2012

Dear Mr. Sharon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120253

Device Name: Elcam Vital Signals Wireless System

Indications for Use:

Elcam Vital Signs Wireless System is indicated for use on patients requiring pressure monitoring.
Elcam Vital Signs Wireless System is intended to perform wireless transmission of pressure information to remote patient monitors from disposable pressure transducers.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120253